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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/780,159	02/17/2004	Joseph DeMeo	KN P 0155	1270
42016	7590	07/12/2006	EXAMINER	
KENSEY NASH CORPORATION 735 PENNSYLVANIA AVENUE EXTON, PA 19341			CHEN, VIVIAN	
			ART UNIT	PAPER NUMBER
			1773	
DATE MAILED: 07/12/2006				

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

10/780,159

Applicant(s)

DEMEO ET AL.

Examiner

Vivian Chen

Art Unit

1773

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 29 March 2006 and 02 May 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-6,8-24 and 28-41 is/are pending in the application.
- 4a) Of the above claim(s) 5,6,8-22 and 41 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-4,23,24 and 28-40 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date 4/2/04; 8/24/05.
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_.

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## DETAILED ACTION

### *Election/Restrictions*

1. Applicant's election without traverse of Group I in the reply filed on 3/29/2006 is acknowledged.
2. Claims 5-6, 8-22, 41 withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on 3/29/2006.

### *Claim Rejections - 35 USC § 112*

1. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.
2. Claims 3, 29 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In claim 3, 29, "DLPLA" appears to be a typographical error or is not defined in the specification.

### *Claim Rejections - 35 USC § 103*

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3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

4. Claims 1-4, 23-24, 28-40 are rejected under 35 U.S.C. 103(a) as being unpatentable over NAKAMURA ET AL (US 2003/0146541), in view of BURKHEAD ET AL (US 2001/0004693).

NAKAMURA ET AL '541 discloses a bone connecting device have a head and shank portion, wherein the shank is molecularly oriented and a head portion which is heated and reshaped and reshaped to have a wider cross-section than the shank portion, wherein the shank portion has regions of lesser and greater orientation. The device comprises a bioabsorbable polymer (e.g., polylactic acid, polyglycolic acid, etc.) and optional reinforcing additives (e.g., alumina, zirconia, etc.). (Figures 3-3C, 6B; paragraphs 0033, 0051, 0059) However, the reference fails to explicitly disclose a device in which the head has less orientation than the shank portion.

BURKHEAD ET AL discloses that it is well known in the art to have the region of reinforcement resulting from molecular orientation concentrated in the shank portion of a bone fixing device and leaving the head portion of a bone fixing device with less reinforcement (i.e., molecular orientation) than the shank portion. (Figure 4A-4D).

It would have been obvious to a person of ordinary skill in the art at the time the invention was made to make an implantable article having varying regions of self-reinforcement

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via molecular orientation in order to selectively increase the mechanical properties in high stress regions. The Examiner has reason to believe that the reheating and forming operations used in NAKMURA ET AL to reshape the head portion would at least partially disrupt the molecular orientation in the head portion, thereby producing a head portion with lesser molecular orientation than the shank portion. Regarding claims 23-24, 32-39, the recited steps are product-by-process limitations and is not further limiting in as so far as the structure of the product is concerned. "[E]ven though product-by-process claims are limited by and defined by the process, determination of patentability is based on the product itself. ***The patentability of a product does not depend on its method of production.*** If the product in the product-by-process claim is the same or obvious from a product of the prior art, the claim is unpatentable even though the prior product was made by a different process." [emphasis added] *In re Thorpe*, 777 F.2d 695, 698, 227 USPQ 964, 966 (Fed. Cir. 1985). See MPEP 2113. Once a product appearing substantially identical is found, the burden shifts to applicant to show a ***unobvious*** difference between the claimed product and the prior art product. *In re Marosi*, 710 F.2d 798, 802, 218 USPQ 289, 292 (Fed. Cir. 1993). See MPEP 2113. If the product in a product-by-process claim is the same as or obvious from a product of the prior art, the product is unpatentable even though the prior product was made by a different process. The patentability of a product is based on the product itself, and is not dependent on its method of production.

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*Conclusion*


5. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Vivian Chen whose telephone number is (571) 272-1506. The examiner can normally be reached on Monday through Thursday from 8:30 AM to 6 PM. The examiner can also be reached on alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Carol Chaney, can be reached on (571) 272-1284. The fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300.

The General Information telephone number for Technology Center 1700 is (571) 272-1700.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

July 7, 2006

  
Vivian Chen  
Primary Examiner  
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